

August 27, 2002

BY FAX

*The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201*

Dear Mr. Secretary:

The American Optometric Association has learned with dismay that the Food and Drug Administration (FDA) may be considering reclassifying tinted plano contact lenses as cosmetics instead of medical devices. We are deeply concerned that such a move will unnecessarily endanger the health of the public.

FDA has historically and correctly classified these lenses as prescription devices since it is necessary for an eye care practitioner to evaluate the ocular health of the patient and the fit of the lens to the eye, just as they would for lenses with corrective power. The physical and other characteristics of these lenses are identical to corrective power lenses; the only difference is the refractive power. More importantly, the very real health considerations associated with improper fit and wearing of lenses applies equally to both non-corrective and corrective power lenses.

Earlier this year the potential risk to wearers of these lenses was dramatized when the sale of over-the-counter tinted lenses in Myrtle Beach, South Carolina, led to a rash of eye injuries, some of them quite serious. Reclassifying these lenses to cosmetics will only lead to increased incidents of this nature.

We are puzzled by this proposed change in policy, given the agency's longstanding and proper concern that consumers be aware of and take steps to minimize the risks associated with improper lens wear. For example, the FDA notes on its web site that "Contact lenses that are not properly fitted by an eye doctor might not work well, or even worse, may harm your eyes (Buying Contact Lenses on the Internet, by Phone or by Mail, Questions and Answers, May 2001).

As noted earlier, that advice should apply equally to non-corrective and corrective power lenses, since both have the same characteristics and pose the same risks if fitted and worn improperly.